(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 March 2003 (20.03.2003)

PCT

(10) International Publication Number
WO 03/022178 A1

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number: PCT/EP02/09931

(22) International Filing Date:
5 September 2002 (05.09.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0121980.7 11 September 2001 (11.09.2001) GB
02252698.2 16 April 2002 (16.04.2002) EP

(71) Applicant *(for all designated States except US)*: **CATHNET-SCIENCE HOLDING A/S** [DK/DK]; Langebjerg 2, Box 218, DK-4000 Roskilde (DK).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **ANDERSEN, Erik** [DK/DK]; Roennens Kvarter 5, Osted, DK-4000 Roskilde (DK). **WEN, Ning** [FR/FR]; 27, allée du Valois, F-60500 Chantilly (FR).

(74) Agent: **BOYDELL, John, Christopher**; Stevens Hewlett & Perkins, Halton House, 20/23 Holborn, London EC1N 2JD (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

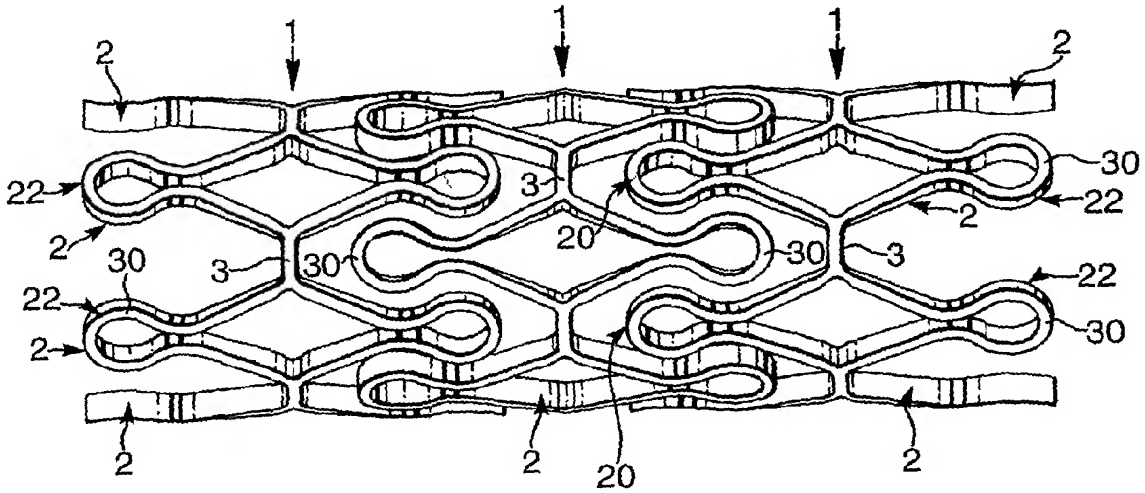
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *with international search report*

[Continued on next page]

(54) Title: EXPANDABLE STENT



(57) Abstract: An expandable stent comprising a tubular body made up of a plurality of separated tubular elements (1) arranged along a common longitudinal axis. Each tubular element (1) comprises a plurality of rhombic-shaped closed cell elements (2) joined by circumferentially extending linking members (3). The closed cell elements (2) are expandable to allow the tubular elements, and hence the stent itself, to expand. In the direction of the longitudinal axis of the stent, the extremities of each of the closed cell elements has an enlarged loop (30) with waisted portions (33) which allow the tubular elements to interlock to create a stable structure, at least when in the unexpanded condition.

WO 03/022178 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

EXPANDABLE STENT

This invention relates to an expandable tubular stent for implantation in the lumen of a body duct in order to ensure a passage therein.

Such stents are used mainly in the treatment of blood vessels exhibiting stenoses, and more generally in the treatment of diseases of various anatomical ducts of the human or animal body, such as, for example, the urinary ducts, especially the urethra, or the digestive ducts, especially the oesophagus.

The percutaneous implantation of an expandable tubular stent in a stenotic blood vessel is generally recommended, for example after a conventional angioplasty procedure, for preventing the dilated vessel from closing up again spontaneously or for preventing its occlusion by the formation of a new atheromatous plaque and the possible recurrence of stenosis.

A known type of expandable tubular stent consists of an assembly of radially expandable, tubular elements aligned along a common longitudinal axis and successively joined together in pairs by respective sets of linking members. Such a stent is disclosed, for example, in international patent application WO 98/58600 in which each of the tubular elements consists of a strip forming a zigzag corrugation defining bent extreme portions which are successively connected together in pairs in opposite directions by rectilinear intermediate portions. By virtue of this zigzag corrugation, the stent is expandable between a first, unexpanded state, enabling it to be implanted percutaneously by means of an insertion device of reduced diameter, and a second, expanded state, in which the stent makes it possible to ensure a passage in the lumen of the body duct. Stents of this type are also disclosed in international patent applications WO 96/26689 and WO 98/20810.

To install the stent, it is placed in the unexpanded state on an angioplasty balloon catheter. Once in place, the balloon is inflated in order

to cause the stent to expand. Alternatively, the stent may be made from a material which has a recovery capacity, so that the stent may automatically expand, once in place.

According to the invention there is provided a stent comprising a tubular body made up of a plurality of separate, radially expandable, tubular elements aligned along a common longitudinal axis, wherein at least some of the tubular elements each comprise a plurality of closed cell elements, each joined to the next by a circumferentially-extending linking member.

It will thus be seen that each tubular element comprises a closed loop consisting of a series of alternating closed cell elements and circumferential linking members.

In most known stents, the tubular elements are physically linked to one another by longitudinally extending linking members. One or more of such longitudinally extending linking members may link each pair of adjacent tubular elements. However, there are a number of advantages to be obtained by not using longitudinally-extending linking members, so that the stent consists simply of a collection of separate tubular members whose alignment along a common axis to form the stent is achieved by other means. Preferably the tubular elements, as well as being expandable, are also compressible.

By "separate" is meant that the tubular elements are not directly connected together by longitudinally-extending linking members. The word "separate" does not imply that the elements may not touch and, as will be explained below, in certain conditions of the stent, the linking members will touch and will indeed link together. In the absence of longitudinally-extending linking members, the structural integrity of the stent is realised by alternative means, such as:-

1) A tubular member or framework which is not directly joined to the adjacent tubular elements but over which or within which the tubular elements are positioned in the desired alignment. For example, the

balloon which is used to expand the stent can be used to maintain the position of the tubular members with respect to one another.

2) Interlock means which mechanically holds the tubular members together even though they are not directly joined. An example of this would be to provide co-operating interlock means on the tubular elements themselves.

In an embodiment of the invention, both these techniques are employed: the tubular elements are placed over the balloon and interlocked together so that the stent remains structurally stable during its often tortuous passage to the treatment site. Upon expansion, the interlocking is released, and the balloon alone then maintains the positional stability of the stent components. After the balloon has been deflated, the expanded stent, which has undergone plastic deformation, maintains its expanded shape and thus keeps the vessel being treated at its desired diameter. The expanded vessel applies a reaction force, due to its elastic nature, against the stent and thus maintains the position of the individual tubular elements making up the stent with respect to one another.

In order to allow the stent to expand it is necessary that the tubular elements be radially expandable. For this purpose, each tubular element is constructed in such a way that it is expandable in the circumferential direction. This may be achieved by the closed cell construction of the invention in which the expansion capabilities of the tubular elements are contained wholly or primarily in the closed cell elements. To avoid out of balance forces during expansion, it is preferred that the closed cell elements be positioned symmetrically with respect to the circumferential linking members, but asymmetric arrangements are also possible.

The tubular elements making up the stent may be all identical, or they may be different – for example, a stent could be made up of a combination of tubular elements comprising closed cell elements, and tubular elements constructed in some other way, arranged to create particular desired properties of the stent as a whole.

The circumferential linking members may simply consist of rectilinear members extending in the circumferential direction. Alternatively the circumferential linking members may be angled to the circumferential direction, so long as they have a component in the circumferential direction so that the adjacent closed cell elements are spaced apart in the circumferential direction. In a further alternative, the circumferential linking members are not rectilinear, but are some other shape to create particular desired characteristics – for example, the circumferential linking members could be such as to provide a degree of flexibility in the circumferential direction, although the expansion capabilities of the tubular element will still be primarily due to the closed cell elements. Preferably, all of the circumferential linking members are the same length in the circumferential direction so that the closed cell elements are evenly distributed about the circumference of the tubular element.

The circumferential linking members attach to the closed cell elements at respective spaced attachment points, and each closed cell element is constructed in such a way that it is capable of expanding from a first position in which the attachment points are relatively close together to a second position in which the attachment points are relatively further apart. In this way, the circumferential length of the tubular element can be increased from a relatively low value, corresponding to the unexpanded condition of the stent, to a relatively higher value, corresponding to the expanded condition of the stent. In one possible construction, each closed cell element comprises two individual members extending between said attachment points, said members being spaced apart in the direction of the longitudinal axis of the stent. Thus, one of said members may be said to be the proximal member, the other the distal member. The proximal and distal members are preferably symmetrically arranged about a straight line joining the two attachment points, this line being coaxial around the circumference with the general direction of the circumferential linking members.

The proximal and distal members are capable of bending in order to enable the expansion of the closed cell element from the first position to the second position. This may be achieved in various ways. For example, each of the proximal and distal members may be fabricated from a flexible member which is thus able to bend to accommodate the required movement. Alternatively, each of the proximal and distal members is fabricated by a plurality of relatively rigid side members joined by hinge members. In the preferred embodiment, each of the proximal and distal members comprises two such side members joined together by a hinge. Preferably the two side members are of equal length, but they do not need to be; however, for a symmetric construction the corresponding side members in each of the proximal and distal members should be of equal length.

In an embodiment, each closed cell element has a generally rhombic or diamond shape, comprising four side members of relatively stiff construction, joined by four hinge members corresponding to the corners of the rhombus. The circumferential linking members attach to the closed cell element at the location of opposite hinge members. Thus, each circumferential linking member has, at one end, one of the hinge members of one closed cell element and, at the opposite end, the opposite hinge member of the adjacent closed cell element.

It is not essential that all the closed cell elements in each tubular element are the same shape. In an alternative embodiment every other closed cell element is of rhombic shape, as described above, whilst the closed cell elements in between comprise "double rhombic" elements, each comprising two rhombic shapes, as described above, aligned in the circumferential direction, but joined by a narrow, but not closed, neck portion.

Other arrangements of closed cell elements are possible, according to the circumstances.

The aforesaid interlock means can conveniently be provided by

providing an enlarged portion at each of the hinge members to which the link members are not attached. The narrowing side members as they approach each hinge member, together with the respective enlarged portion, form a narrow or waist portion which can overlap with an enlarged portion from the next adjacent tubular element. Two such waist portions acting together can thus retain an enlarged portion from the next adjacent tubular element.

The interlock means do not have to be provided on every closed cell element. It may be adequate to provide them on just a few closed cell elements, but evenly spaced about the circumference, so as to give a balanced attachment between adjacent tubular elements. For this purpose some of the closed cell elements may extend further in the axial direction of the stent than the remaining closed cell elements, so that these extended portions may interlink with the adjacent tubular element.

This enlarged portion can be formed as a flexible open cell with a narrowed neck, or can be formed as a relatively rigid block, from which, for example, the two side members may emerge via a respective narrowed portion to act as a hinge – in this latter case, the hinge member actually consists of two separate hinges.

In current medical practice, it is often the case that, in addition to its role in providing ongoing support for the vessel wall, the stent is required to act as a means whereby therapeutic agents may conveniently be applied. Indeed the trauma caused during the angioplasty procedure may call for localised drug treatment. In addition, drugs may be used to counteract restenosis, and for other purposes. Conventionally, such therapeutic agents are contained within some form of coating which is applied to the stent so that the drug will be released over a period of time. One problem with such an arrangement, however, is that, whereas the drug needs primarily to be applied through the wall of the vessel being treated, in practice as much of the drug is released into the fluid, e.g. blood, flowing within the vessel as passes through the vessel wall. Not only is the drug

which is washed away effectively wasted, it can also do positive harm elsewhere if, for example, it enters a sensitive organ such as the heart.

Thus, in an embodiment of the invention the stent is equipped with wells opening into its exterior surface – that surface which, when the stent is in place, will face the wall of the vessel being treated – said wells being suitable to contain therapeutic agent.

The wells may comprise holes or grooves opening into the exterior surface of the stent, and may or may not pass right through the material of the stent to the interior of the stent. However, if the wells pass through to the interior of the stent there is clearly a danger of at least some of the drug being released into the fluid flowing within the vessel. Therefore it is preferred that, in such a case, that end of the well which opens into the interior of the stent is constructed, for example by being made narrower, and/or being plugged by a material which prevents or considerably reduces the tendency of the therapeutic agent to flow therethrough.

Thus it is preferred that the well is wholly or primarily open to the exterior surface of the stent so that the therapeutic agent may act directly on the wall of the vessel and does not get washed away by the fluid flowing along the vessel being treated.

The wells may open onto any suitable exterior surface of the stent. For example, the wells may conveniently be formed in the blocks which form the enlarged portions of the closed cell elements. For example, each block could be formed with a well in the form of a hole, which may or may not be a through hole and which opens into that surface of the block which forms part of the exterior surface of the stent. Alternatively the wells may be formed as grooves in the side members of the closed cell elements, the grooves opening into that surface of the side members which forms part of the exterior surface of the stent. It will be understood, however, that the above positions are given just as examples.

As mentioned above, the wells contain therapeutic agents which are intended to be released at a controlled rate against the wall of the vessel

being treated. Not all of the wells necessarily will contain the therapeutic agent, and not all wells need to contain the same therapeutic agent. It is possible, for example, that the wells of different tubular elements contain different therapeutic agent, opening up the possibility of providing mixtures of drugs by choosing particular tubular elements carrying particular drugs to make up the stent. Clearly this is particularly easy with a stent in which the tubular elements are separate from one another. The therapeutic agents may also be provided in separate layers within the well, with the drug needed first being in the top layer, and the drugs needed later in lower layers, in correct sequence.

In addition, it is possible to provide that some of the wells contain therapeutic agents which have different rates of release. For example the drug contained in the wells of those tubular elements at or near the ends of the stent could be arranged to have a more rapid or a slower release rate than the remainder.

The therapeutic agents may be provided in any suitable form for retention in the wells, and for sustained release, once installed within the vessel. Examples are liquid, gel or powder form.

In order that the invention may be better understood, several embodiments thereof will now be described by way of example only and with reference to the accompanying drawings in which:-

Figure 1 is a two-dimensional view of the evolute of the surface of a stent according to a first aspect of the present invention, in its "as cut" condition;

Figure 2 is a view corresponding to Figure 1, but showing just a single tubular element;

Figure 3 is an enlarged view of one of the closed cell elements in the embodiment of Figure 1;

Figures 4A and B are side and perspective views of the stent of Figure 1, but in which the number of elements is just three, in its "as cut" condition;

Figure 5 is a perspective view of a single tubular element from the stent of Figure 1;

Figures 6 and 7 are views similar to Figures 4A and 4B respectively, but showing the stent in the crimped condition;

Figures 8 and 9 are views similar to Figures 4A and 4B respectively, but showing the stent in the expanded condition;

Figures 10 and 11 are views similar to Figure 4B, but showing two further embodiments showing both the first and second aspect of the invention;

Figure 12 is a view similar to Figure 2 showing a still further embodiment of the invention;

Figures 12A, B and C are views on the lines A-A, B-B and C-C respectively of Figure 12;

Figure 13 is a view similar to that of Figure 5, but showing the embodiment of Figure 12;

Figure 14 is an enlarged view of part of Figure 13;

Figure 15 is a view similar to Figure 2 showing a still further embodiment of the invention;

Figures 15A and B are views on the lines A-A and B-B respectively of Figure 15;

Figure 16 is a view similar to that of Figure 5, but showing the embodiment of Figure 15;

Figure 17 is an enlarged view of part of Figure 16;

Figure 18 is a view similar to Figure 2 showing a still further embodiment of the invention;

Figure 18A is a view on the line A-A of Figure 18;

Figure 19 is a view similar to that of Figure 5, but showing the embodiment of Figure 18;

Figure 20 is a view similar to Figure 2 showing a still further embodiment of the invention;

Figure 21 is a view similar to Figure 5, but showing the embodiment

of Figure 20,

Figure 22 is a view similar to Figure 2 showing a still further embodiment of the invention;

Figure 23 is a view similar to Figure 5, but showing the embodiment of Figure 22; and

Figure 24 is a view similar to Figure 4b, but showing the embodiment of Figure 22.

Referring firstly to Figures 1 and 4, the stent comprises a series of radially expandable tubular elements 1 aligned along a common longitudinal axis. Both of these Figures show the stent in its "as cut" condition by which is meant the condition in which it comes out of the manufacturing process. Figure 1 illustrates the stent folded out in two dimensions, illustrated by the X-Y coordinates printed to the side of the drawing. In practice the stent is, of course, a three dimensional object, as illustrated in elevation and in perspective in Figures 4A and 4B respectively; thus it is assumed that the ends 12, 13 of each tubular element in Figure 1 are in fact joined so that each element forms a closed loop of generally tubular configuration. In this description the longitudinal direction of the stent is parallel to the X-axis illustrated in Figure 1, while the circumferential direction of the stent is parallel to the Y-axis in Figure 1.

It will be noted that the tubular elements 1 are separate from one another in the sense that there is no direct physical link between them, keeping the tubular elements 1 in position. Instead alternative means are used to maintain the structural integrity of the stent. This will be explained in more detail below.

In the stent illustrated, all of the tubular elements are identical in structure and size although, as mentioned above, this need not necessarily be the case. A single tubular element 1 is shown, in two dimensional form in Figure 2, and in three dimensional form in Figure 5. Each tubular element comprises a plurality of closed cell elements 2 equally spaced apart by circumferentially extending linking members 3. In the embodiment

illustrated each tubular element 1 comprises six closed cell elements 2, spaced apart circumferentially by 60°, but other numbers of closed cell elements are possible, according to the circumstances.

A single closed cell element 2 is shown in enlarged detail in Figure 3. The closed cell element has a generally rhombic or diamond shape defined by four side members 24 to 27 joined together by respective hinge members 20 to 23. The circumferential linking members 3 attached to respective opposite hinge members 21, 23.

The hinge members 21, 23 are formed by narrowed sections 28, 29 where the respective side members 24/27, 25/26 join the respective linking member 3. The hinge members 20, 22 are formed as a loop 30 having a narrowed opening 31 into the interior 32 of the cell element. This narrowed opening 31 corresponds to a waisted portion 33 which cooperates in the interlocking of individual tubular elements 1, as will be explained below.

Before the stent is used, it will generally be crimped to the balloon which will carry it to the treatment site and subsequently expand it. The crimping process involves compressing the "as cut" stent onto the balloon so that it is securely gripped. During compression the diameter of the tubular elements, decreases and this is achieved by a deformation of the closed cell elements 2 in such a way as to tend to close the elements up – i.e. so that the hinge members 21 and 23 move towards one another, thus reducing the circumferential length of the tubular element 1. During this process the closed cell elements bend at the hinge members 20 to 23. the crimped condition of the stent is illustrated in Figures 6 and 7 and since, in effect, the stent is expanded from this condition, the crimped condition can also be regarded as the unexpanded condition of the stent.

It will be noted in Figures 6 and 7 that, in the crimped condition of the stent, the hinge members 20, 22 belonging to adjacent tubular elements are interlocked, thus maintaining the structural integrity of the stent as a whole. This interlocking is achieved by the cooperating interlocking shapes of the hinge members 20, 22 in which each of the

enlarged loops 30 lie between a pair of waisted portions 33 belonging to circumferentially adjacent closed cell elements 2 belonging to the same tubular element 1. By careful design, the closed cell elements can be configured to grip one another to maintain the shape of the stent so that it is not dislodged or deformed during its often long and tortuous passage to the treatment site. The longitudinal flexibility of the stent is ensured in the crimped condition by the fact that each loop 30 is allowed to move longitudinally a short but controlled distance towards the adjacent linking member 3. Thus, as the stent is bent longitudinally the loops 30 on one side move slightly, as described, whilst those on the other side move in the opposite direction. In an alternative embodiment (not shown) still greater longitudinal flexibility can be achieved by arranging that the elements are interlocked in such a way as to allow the loops to move, in a controlled manner, in either longitudinal direction.

When the stent reaches the treatment site, and the physician is satisfied as to its correct position, the balloon carrying the stent is expanded, in the known manner, to expand the stent from its condition shown in Figures 6 and 7 to its dilated condition shown in Figures 8 and 9. During this expansion process, the closed cell element 2 deform to a final shape clearly illustrated in Figure 8. It will be seen that the hinge members 21, 23 have moved apart in the circumferential direction, thus increasing the circumferential length of each tubular element 1. At the same time, the hinge members 20, 22 of adjacent closed cell elements 2 move apart in the circumferential direction thus releasing the grip which they had previously exerted on the corresponding members of adjacent tubular elements. The stent however by now is supported both from within and without and so maintains its structural shape, even though the interlocking is released. The support from within comes from the balloon which is being internally pressurised to expand the stent; the support from without comes from the wall of the vessel being treated.

It will also be noted that, during expansion, the length, in the

longitudinal direction of the stent, of each of the closed cell elements 2 reduces and this effect, in a stent with linking members between adjacent tubular elements, causes the overall length of the stent to reduce. This reduction in length is undesirable for various reasons, and it will be seen that the use of independent tubular elements 1 substantially eliminates this problem.

Figures 10 and 11 show modified versions of the stent of Figure 1 in which the hinge members 20, 23 are modified from the open loop form described previously.

The stents of Figures 10 and 11 differ from that of Figure 1 in that the hinge members 20, 22 comprise a block 34 of material from which the side members 24/27 and 25/26 emerge, via a respective narrowed portion to act as a hinge. Thus, in this case the hinge members 20, 22 each comprise a pair of hinges by which the respective side members 24/27 and 25/26 are attached to the blocks 34. Preferably these blocks 34 are formed integrally with the remainder of the tubular element, and are of the same material.

The difference between the embodiments of Figures 10 and 11 is in the shape of the blocks 34 which in the case of Figure 10 is substantially rectangular and in the case of Figure 11 is substantially circular. In both cases, each block 34 acts as an enlarged end in a similar manner to loop 30 of the Figure 1 embodiment, and defines a narrowed waist portion where it joins the adjacent side members. The arrangement is thus able to interlock the individual tubular elements 1 in the same way as described above.

The advantages of a stent with independent tubular elements over one in which the tubular elements are linked by linking members can be summarised as follows:-

1) Manufacture is made easier because only a basic tubular element has to be cut. Any stent length can readily be created by adding the appropriate number of tubular elements at the commencement of the

assembly or crimping process.

2) The crimped stent has a high degree of longitudinal flexibility since it is not restrained by the inter-element linking members of known stents.

3) The crimped stent has a high degree of longitudinal conformability due to its tubular elements being interlocked at multiple cell locations.

4) There is substantially no shortening of the stent during expansion because the shortening of each tubular element does not affect the stent as a whole.

5) Once deployed, the stent has a high degree of longitudinal flexibility and of longitudinal and radial conformability due to the absence of the restraint imposed by inter-element linking members.

6) Once deployed the stent has a good vessel repartition and vessel scaffolding, with homogeneous support for the vessel wall – see particularly Figure 8.

Figures 10 and 11 also illustrate the use of wells for containing therapeutic agent. It will be seen that, in each of Figures 10 and 11 the blocks 34 have formed on their exterior surface a well 35 which is intended to act as a reservoir for a therapeutic agent. Each well 35 takes the form of a shallow blind hole which opens into the exterior surface which, when the stent is deployed faces the wall of the vessel being treated.

Thus, any therapeutic agent contained within the wells 35 acts directly on the wall of the vessel, and is not substantially affected by the flow of fluid within the vessel.

Although only a single well 35 is formed in each block 34, it is possible for multiple smaller wells to be formed, perhaps each containing different drugs. Different drugs can be supplied on different tubular elements, making it easy to create a stent, as needed, containing an appropriate recipe of drugs.

The holes making up the wells 35 can be formed as through-holes, and plugged from the interior side to create a blind hole. Alternatively, the through hole can be left, and a suitable substance which will resist the

washing away of the drug contained within the well can be deposited at the inner end of the through hole.

Although the wells 35 are shown as circular holes, it will be understood that other shapes are possible, including multi-sided, square or rectangular. Alternatively, the wells can be formed as grooves or slots opening into the exterior surface of the block 34.

The wells may additionally or instead of be provided at other locations, such as on the side members 24 to 27 of the closed cell elements 2. However, for this purpose, the side members would have to be made less deformable than they might otherwise be since any deformation of the reservoir during stent crimping or deployment might result in delamination of the reservoir contents, which would be undesirable. The blocks 34 are seen as attractive since they suffer substantially less deformation than other parts of the stent because their bulk, relative to the remaining components of the stent, is such that they are relatively stiff.

Figures 12 to 19 illustrate further embodiments similar to that of Figures 10 and 11, showing alternative arrangements of wells.

In the embodiment shown in Figures 12 to 14, two shapes of wells are shown. Half of the wells 35 have the shape of a short slot 36 which opens only into the exterior surface of the tubular element; the other half of the wells 35 have the shape of a slot 37 which opens both into the exterior surface of the tubular element 1, but also into the edge of the tubular element 1. Various combinations of these shaped wells can be used.

The enlarged view of Figure 14 is of interest in that it clearly shows the structure of the left-hand hinge member 20. This can be seen to comprise two narrowed (i.e. less wide) portions 50,51 where the respective side members 24 and 27 join the block 34.

In the embodiment of Figures 15 to 17, there is again a combination of different well shapes: a first type of well 35 formed of a short slot 38 extending in the circumferential direction of the stent; a second type of well

35 formed of a slot 39 which extends right across the block 34 in the circumferential direction of the stent, and is open at both ends.

Figures 18 and 19 show an embodiment in which again two different styles of well 35 are shown. On the left hand side a block 40 is formed within the loop 30 of a hinge member of the type described above in relation to the embodiment of Figure 1. The block 40 is formed with a well 35 formed as a blind hole, in a similar manner to the wells 35 of the embodiment of Figure 11.

On the right hand side a block 41 is formed outside of the loop 30 and, once again, is equipped with a well 35 in the form of a blind hole. Since there is room beyond the hinge members 20, 22, the block 41 does not interfere with the interlocking of the tubular element 1 together during crimping, as described above.

The advantages of stents incorporating wells, as described above, can be summarised as follows:-

1) The well can hold drugs without the need for a polymer matrix coating. The use of wells can eliminate coating delamination during stent deployment, thus reducing the risk of thrombosis.

2) The absence of a polymer matrix coating eliminates any potential biocompatibility problems arising from their use.

3) Once the stent is fully deployed, the outside surface of the stent is pushed against the wall of the vessel being treated; this means that the well is open only towards the vessel wall, to enable diffusion of the drugs into the vessel wall. In addition, the drug cannot be washed out by the flow of fluid in the vessel and so cannot have undesired effects elsewhere.

4) Compared to a thin (0.1 – 5 micron) drug layer coated on the stent, the reservoir can be loaded with a high dose and long life time.

5) The reservoir dimensions (diameter, length, width, depth) can be readily varied to the particular circumstances such as blood flow direction and drug release kinetics.

6) Each well can contain a single drug and therefore different drugs can be individually held in different wells without the danger of their reacting with each other.

Figures 20 to 24 show two further embodiments in which the closed cell elements in each tubular element 1 are not all identical, and in which the locating means are not provided on every closed cell element.

Referring to Figures 20 and 21, there is shown an embodiment in which each tubular element 1 is made up of two different shapes of closed cell element which alternate around the tubular element. The first shape of closed cell element, illustrated under reference 50 is similar to that of the closed cell elements described above with reference to Figure 3, except that the loops 30 on one side of the rhombic shaped structure are positioned at the end of a pair of extended arms 51,52. As a result these "extended" loops 30 protrude, in the axial direction of the stent, with respect to the remaining parts of the tubular element 1, and are thus able to interlock with the next adjacent tubular element.

Figures 22 to 24 illustrate an embodiment similar to that of Figures 20 and 21 but in which the extended loops 30 are open at their neck, as distinct from the arrangement in Figures 20 and 21, where each extended loop 30 takes the form of a closed ring which is attached at the ends of the arms 51,52.

In both embodiments, the closed cell elements between the elements 50 are of different shape to the elements 50. These elements, given the reference 53, each comprise two rhombic-shaped sections 54,55 which are joined by a narrow open neck portion 57.

The joining of adjacent tubular elements is shown in Figure 24. Figure 24 actually shows the embodiment of Figures 22 and 23, but it will be understood that the same interlocking technique can be used for the embodiment of Figures 20 and 21. In relation to Figure 24, it should also be noted that the drawing shows the tubular elements in their expanded

state – i.e. in a state in which they would not ordinarily be interlocked – see above.

The aperture 56 formed within the loop 30 in the embodiment of Figures 20 and 21 could be used as a well for containing a therapeutic agent, in the manner described above. For this purpose, the aperture 56 may be a through aperture, plugged at its inner end, or may be a blind bore, opening into the outer surface only.

The stent which has been described is expandable between an unexpanded state (in practice, probably the crimped condition mentioned above), in which it is able to be guided inside the lumen through a body duct, such as a blood vessel, for example, and an expanded state, in which the stent, after a uniform expansion, comes into contact with the inner wall of the body duct, defining a passage of approximately constant diameter inside said duct.

The stent will generally be forcibly expanded mechanically under the action of a force exerted radially outwards, for example under the effect of the inflation of a balloon. However, the stent may be of the "auto-expandable" type, i.e. capable of changing by itself from a first, unexpanded condition under stress, enabling it to be guided through the body duct, to a second, expanded, working condition.

The stent may be made of any material compatible with the body duct and the body fluids with which it may come into contact.

In the case of an auto-expandable stent, it will be preferable to use a material with a recovery capacity, for example, stainless steel, Phynox® or nitinol.

In the case of a stent utilising a forced expansion, a material with a low elastic recovery capacity may be used to advantage. Examples are metallic materials such as tungsten, platinum, tantalum, gold, or stainless steel.

The tubular elements 1 may be manufactured from a hollow tube with an approximately constant thickness corresponding to the desired

thickness. The shape of the tubular elements may be formed either by laser cutting followed by electrochemical polishing, or by chemical or electrochemical treatment.

The tubular elements may alternatively be manufactured from a sheet of approximately constant thickness corresponding to the desired thickness of the stent. The geometric configuration of the tubular elements can be obtained either by laser cutting followed by electrochemical polishing, or by chemical or electrochemical treatment. The sheet cut in this way is then rolled up to form a cylinder and welded to give the desired final structure.

After assembly of the tubular elements 1 into a stent of the desired length, the stent can be deployed in a manner known per se. In the case of a stent utilising mechanically forced expansion, the insertion system will preferably comprise a balloon catheter onto which the stent will be crimped in the unexpanded state before being introduced into an insertion tube for guiding it to the site to be treated.

The stent of the invention can be intended for both temporary or permanent placement in the duct or vessel to be treated.

CLAIMS

1. A stent comprising a tubular body made up of a plurality of separate, radially expandable, tubular elements aligned along a common longitudinal axis, wherein at least some of the tubular elements each comprise a plurality of closed cell elements, each joined to the next by a circumferentially-extending linking member.

2. A stent as claimed in claim 1 wherein the tubular elements are also compressible.

3. A stent as claimed in either one of claims 1 or 2 further including interlock means for mechanically holding the tubular elements together, at least in an unexpanded condition of the stent.

4. A stent as claimed in claim 3 in which said interlock means are provided by inter-engaging elements provided on said tubular elements.

5. A stent as claimed in claim 4 wherein each of said closed cell elements is provided with a respective inter-engaging element which engages a corresponding inter-engaging element on an adjacent tubular element.

6. A stent as claimed in any one of claims 1 to 4 wherein some, but not all, of said closed cell elements are provided with a respective inter-engaging element which engages a corresponding inter-engaging element on an adjacent tubular element.

7. A stent as claimed in any one of the preceding claims wherein each closed cell element is expandable in the circumferential direction of the tubular element, thus allowing the tubular element to expand and contract.

8. A stent as claimed in claim 7 wherein each closed cell element is positioned symmetrically with respect to the circumferential linking members.

9. A stent as claimed in either one of claims 7 or 8 wherein each closed cell element comprises two attachment points at each of which it joins to a respective circumferential linking member, and wherein the closed cell

element is such as to be capable of expanding from a first position in which the attachment points are relatively close together, to a second position in which the attachment points are relatively further apart.

10. A stent as claimed in claim 9 wherein, between said attachment points, each closed cell element comprises proximal and distal members, mutually spaced apart in the direction of the longitudinal axis, said proximal and distal members being capable of bending to accommodate the expansion from the first position to the second position.

11. A stent as claimed in claim 10 wherein the proximal and distal members of each closed cell element are joined together at each of their circumferentially spaced ends by means of a respective hinge member.

12. A stent as claimed in claim 11 wherein each hinge member is attached at one end of a respective circumferentially-extending linking member, the other end of the linking member having attached thereto the opposite hinge member of the next adjacent closed cell element.

13. A stent as claimed in any one of claims 10 to 12 wherein the proximal and distal members each comprise a flexible member joining the attachment points.

14. A stent as claimed in any one of claims 10 to 12 wherein the proximal and distal members each comprise two or more relatively rigid side members joined by a hinge.

15. A stent as claimed in claim 14 wherein said four side members together form the shape of a rhombus.

16. A stent as claimed in either one of claims 14 or 15 wherein each of said side members is of rectilinear shape.

17. A stent as claimed in claims 5 or 6 and any one of claims 10 to 16 wherein said inter-engaging elements are each formed by a respective loop formed by each of said proximal and distal members.

18. A stent as claimed in any one of claims 14 to 16 wherein the hinge joining each of said two side members comprises a loop which forms one of said inter-engaging elements, and wherein the loop joins the adjacent

side members by a waisted portion which, together with the corresponding waisted portion from the next adjacent closed cell element in the same tubular element, forms a co-operating inter-engaging element.

19. A stent as claimed in any one of the preceding claims wherein all of the closed cell elements making up each tubular element are of the same shape.

20. A stent as claimed in any one of claims 1 to 18 wherein some of the closed cell elements making up each tubular element are of a different shape to the remainder.

21. A stent as claimed in any one of the preceding claims wherein the exterior surface of the tubular body is equipped with wells which open onto its exterior surface, said wells being suitable to contain one or more therapeutic agents.

22. A stent as claimed in claim 21 in which the wells comprise holes or grooves opening into the exterior surface of the stent.

23. A stent as claimed in claim 22 wherein the holes or grooves are blind, i.e. do not pass through the material of the stent.

24. A stent as claimed in claim 22 wherein the holes or grooves pass through to the interior of the stent.

25. A stent as claimed in claim 24 in which the inner end of the hole or groove is plugged by a material which prevents or considerably reduces the flow of therapeutic agent therethrough.

26. A stent as claimed in claim 25 wherein said material is, or contains, therapeutic agent.

27. A stent as claimed in any one of claims 21 to 26 wherein the closed cell elements are formed with blocks on each of which are formed one or more of said wells.

28. A stent as claimed in any one of claims 21 to 27 wherein at least some of said wells contain multiple therapeutic agents arranged in layers so as to release in sequence.

Fig.1.

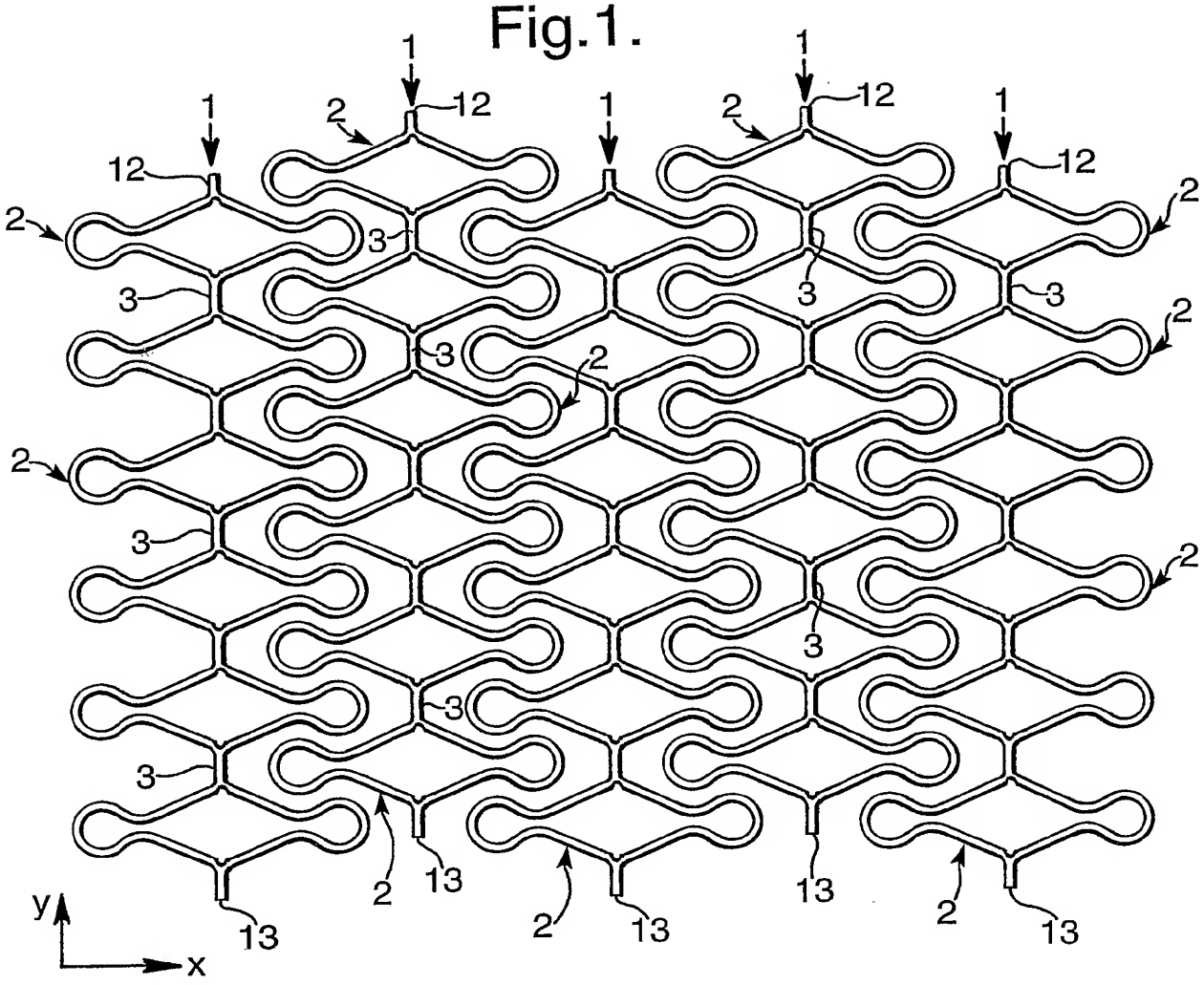


Fig.2.

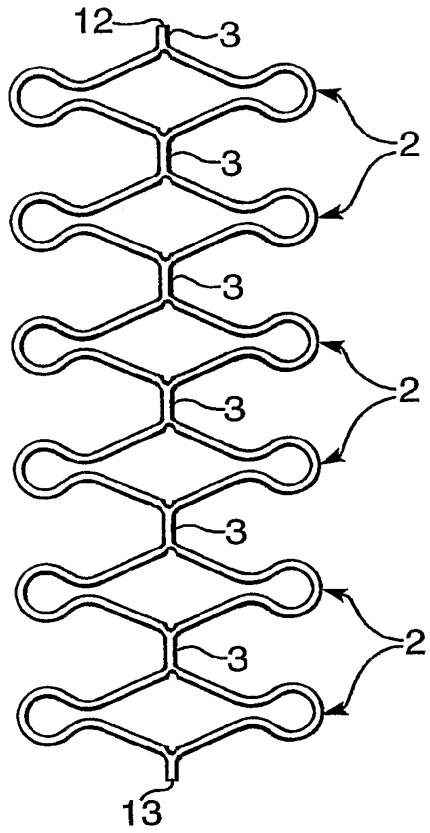

12
3
2
3
3
2
3
3
2
3
13

Fig.3.

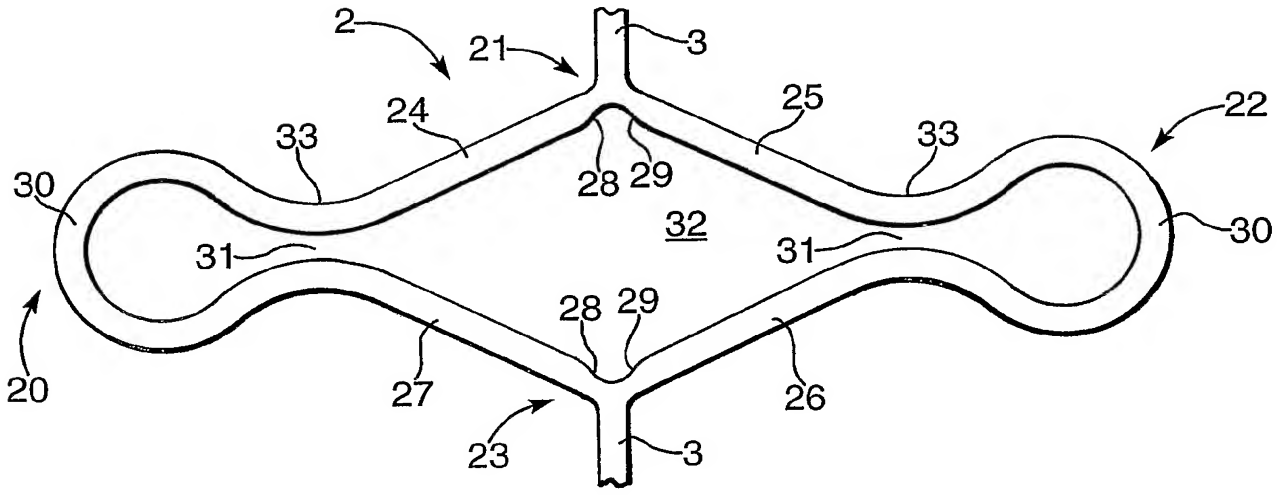

2
21
3
24
25
22
33
33
30
28
29
32
30
31
31
28
29
20
27
26
23
3

Fig.4A.

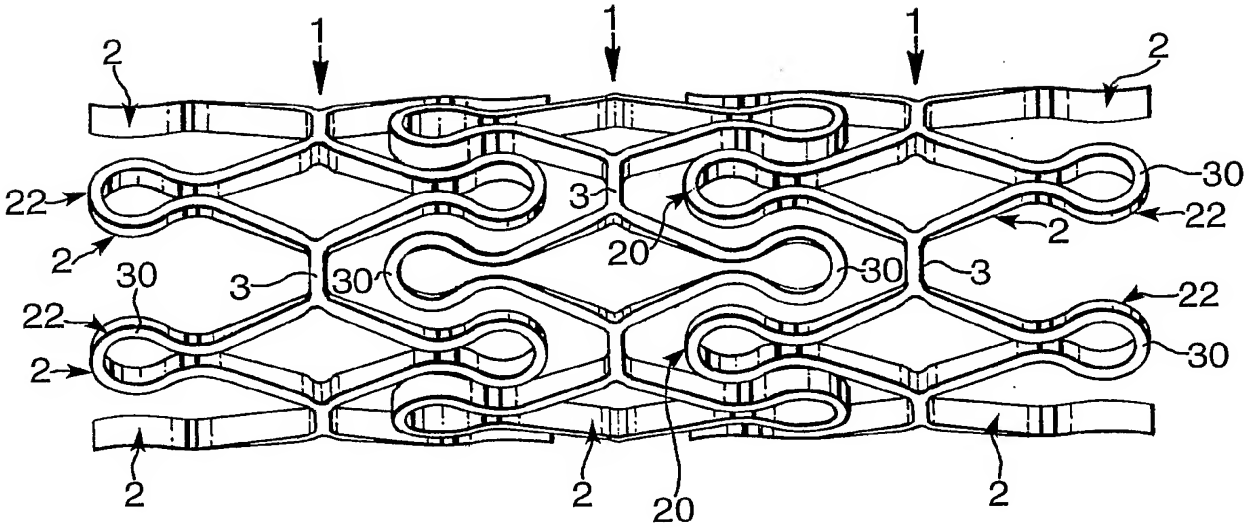


Fig.4B.

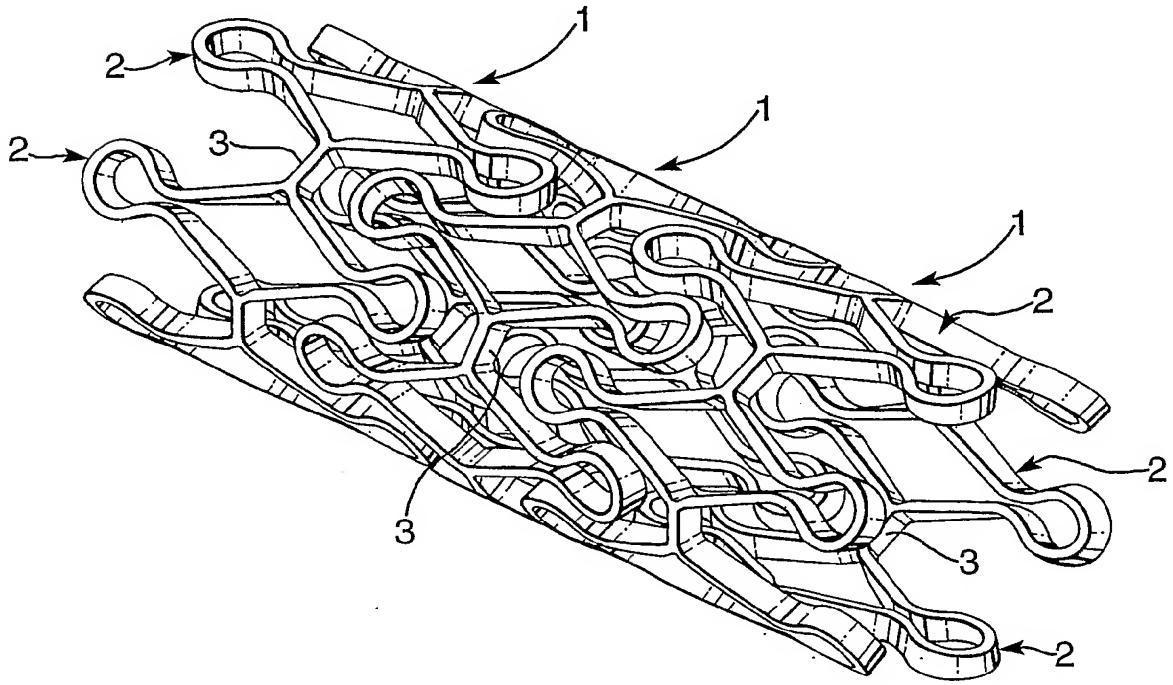


Fig.5.

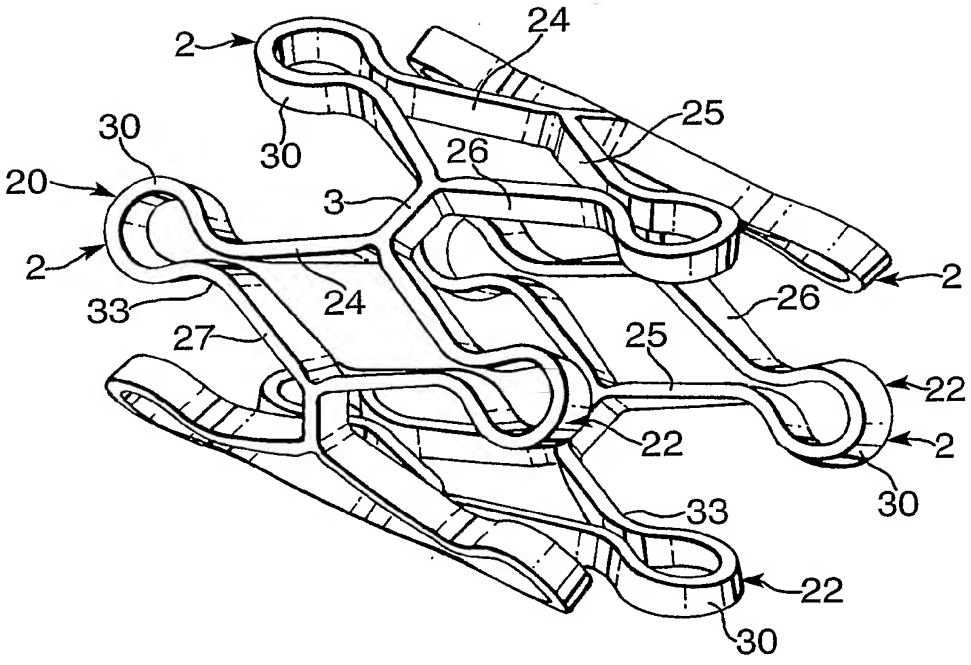


Fig.6.

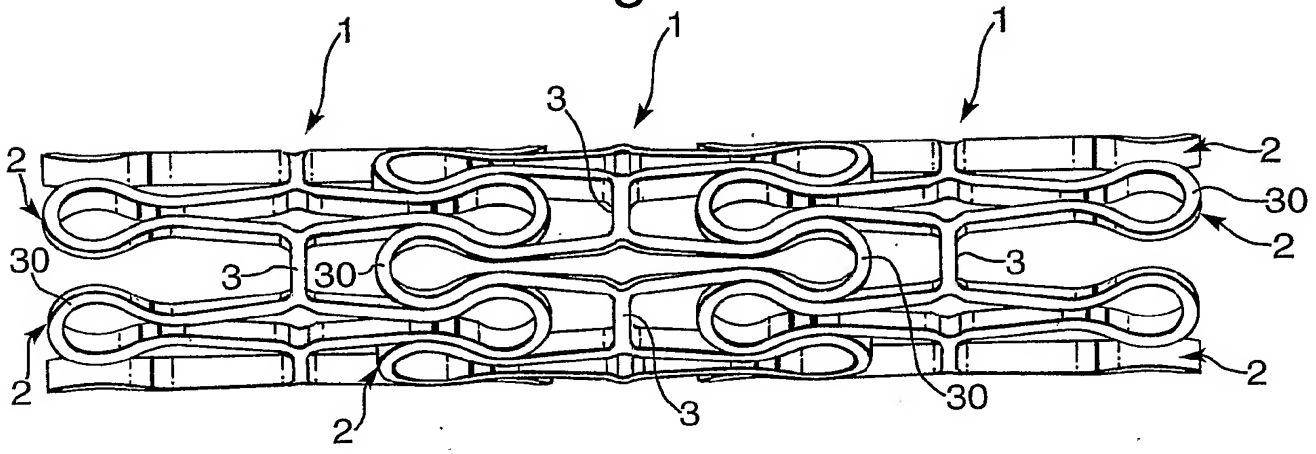


Fig.7.

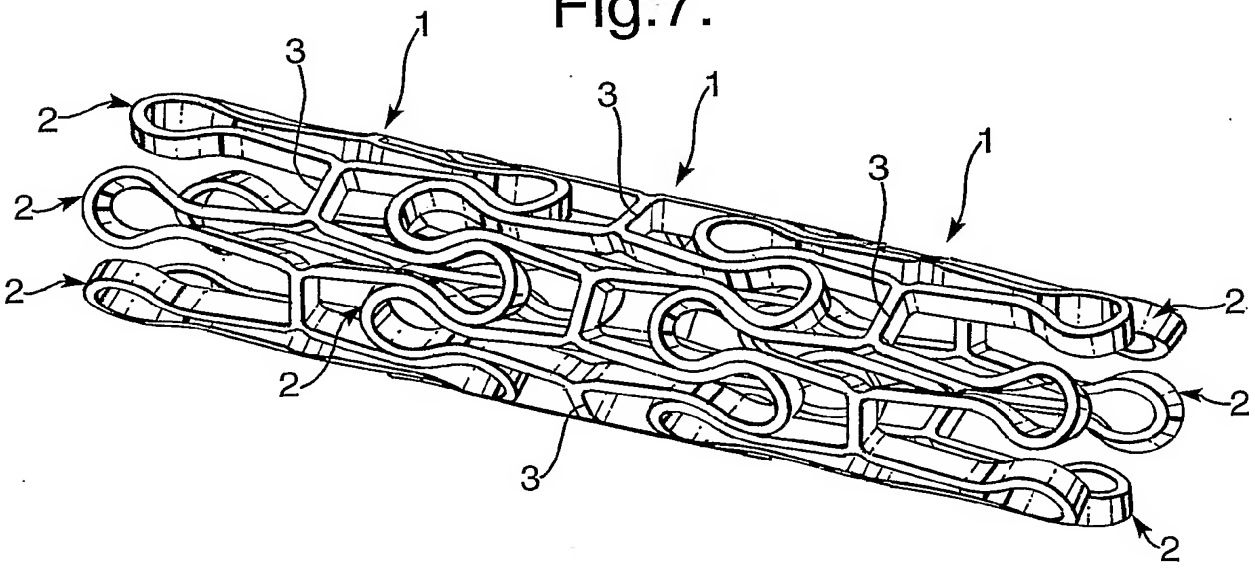


Fig.8.

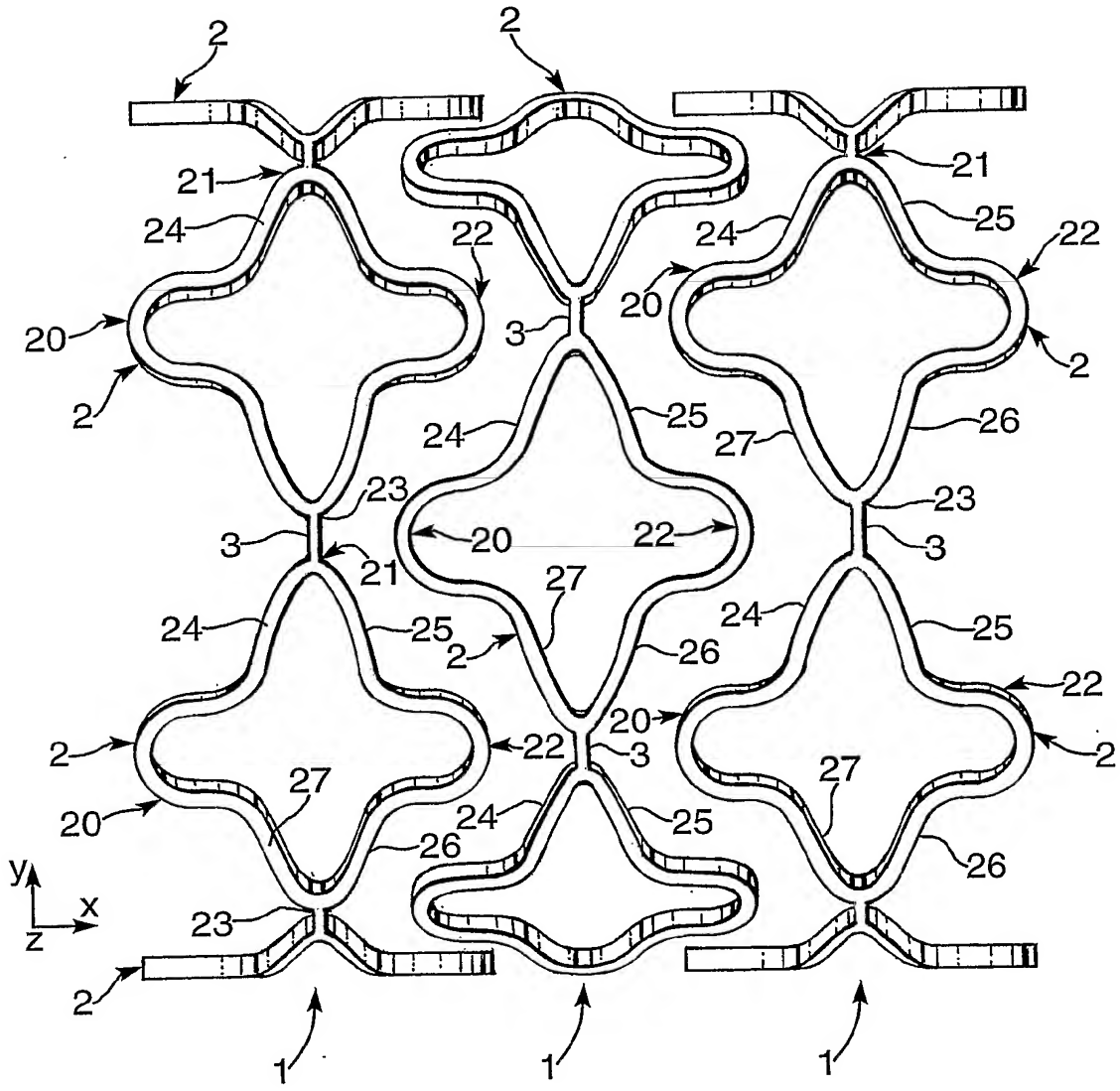

2
2
21
21
24
22
24
25
22
20
20
3
2
2
24
25
27
26
23
23
3
20
22
3
21
27
24
25
24
25
2
26
22
20
2
22
3
2
27
27
20
24
25
26
26
y
x
z
23
2
1
1
1

Fig.9.

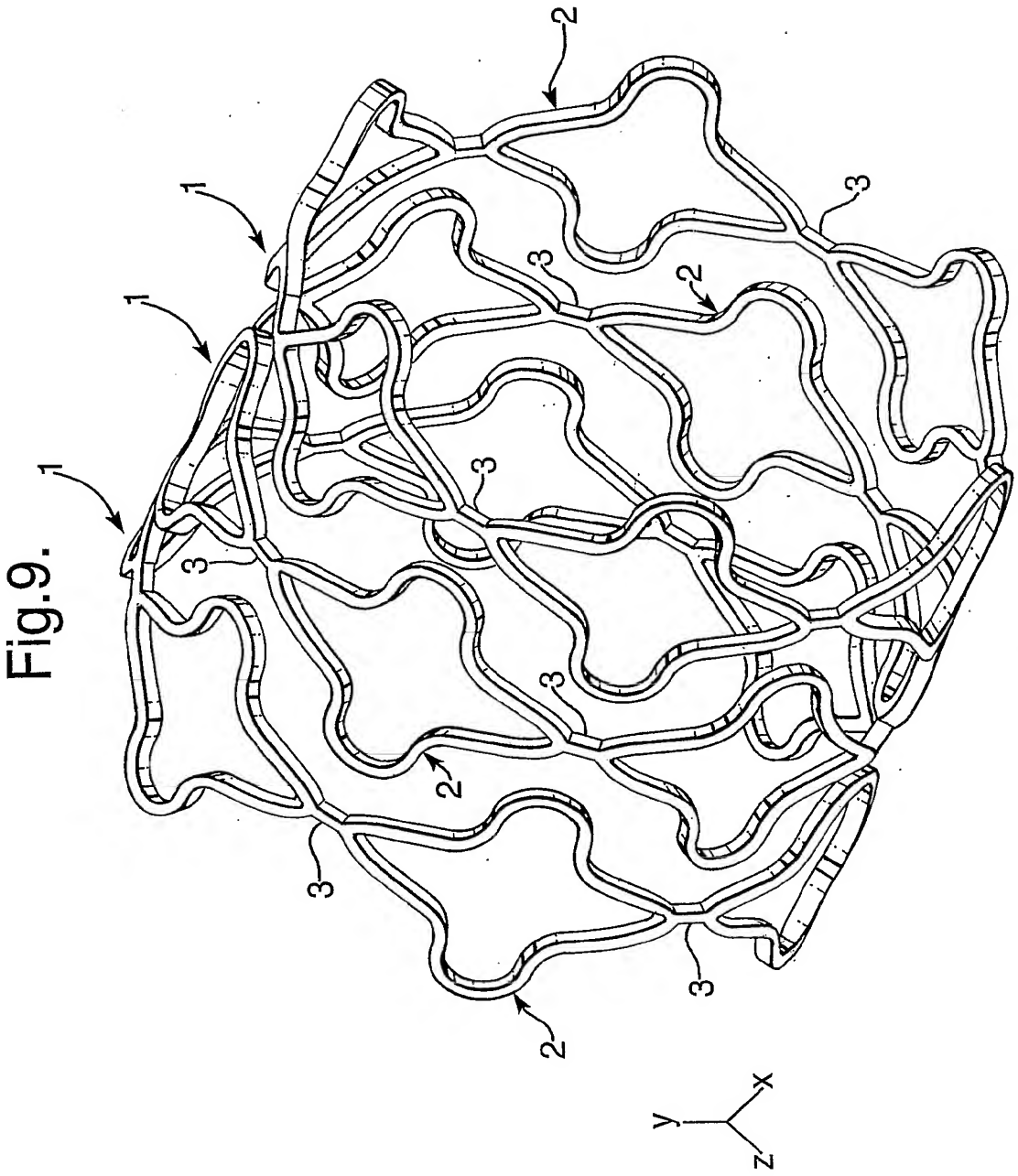


Fig.10.

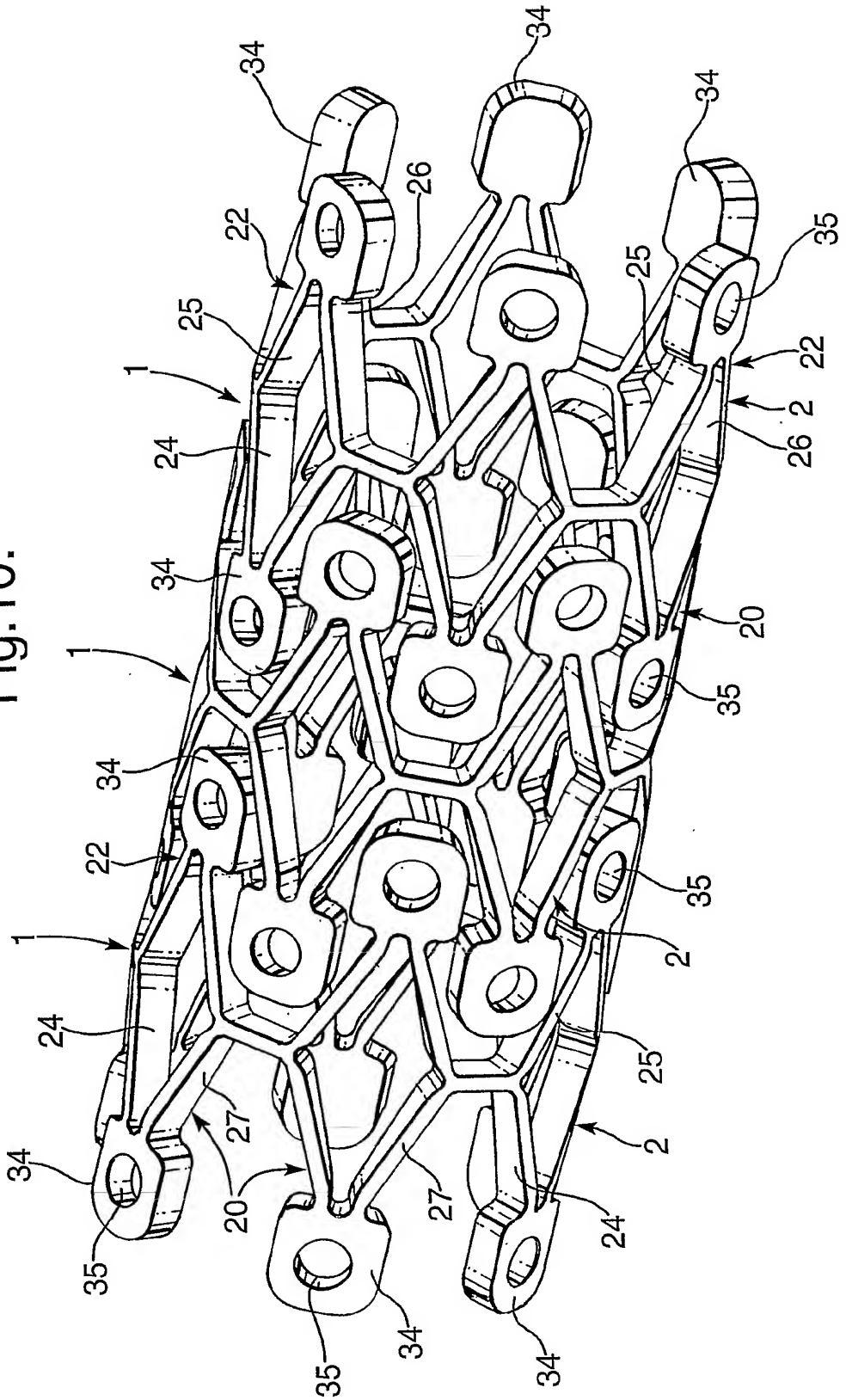

34
34
34
26
22
25
25
35
1
22
2
24
26
34
20
1
35
34
22
35
1
2
24
25
27
2
34
20
27
24
35
34
34

Fig.11.

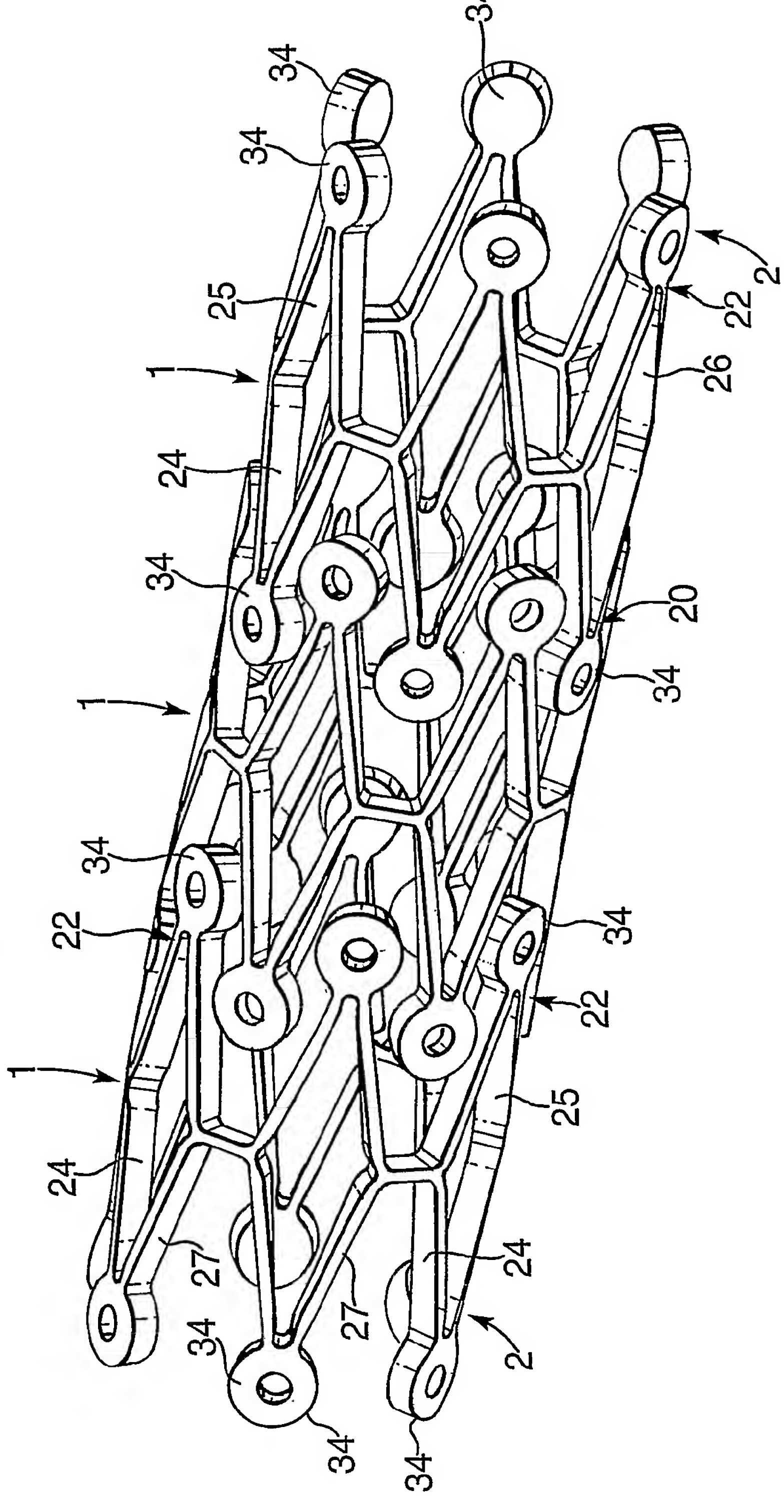


Fig.12A.

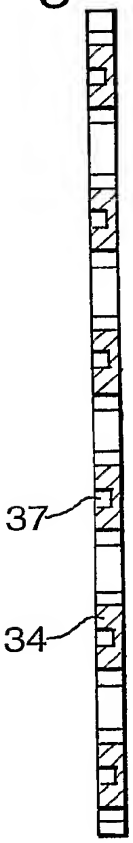


Fig.12.

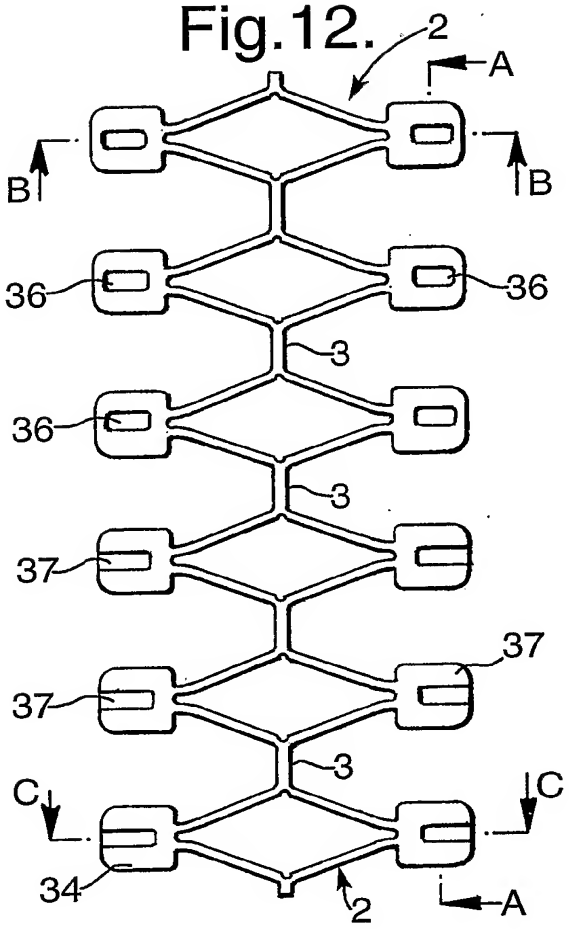


Fig.12B.

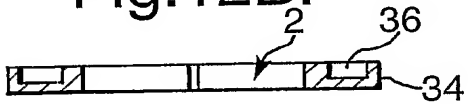


Fig.12C.

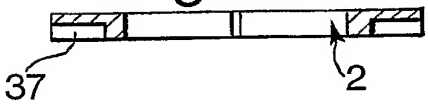


Fig.13.

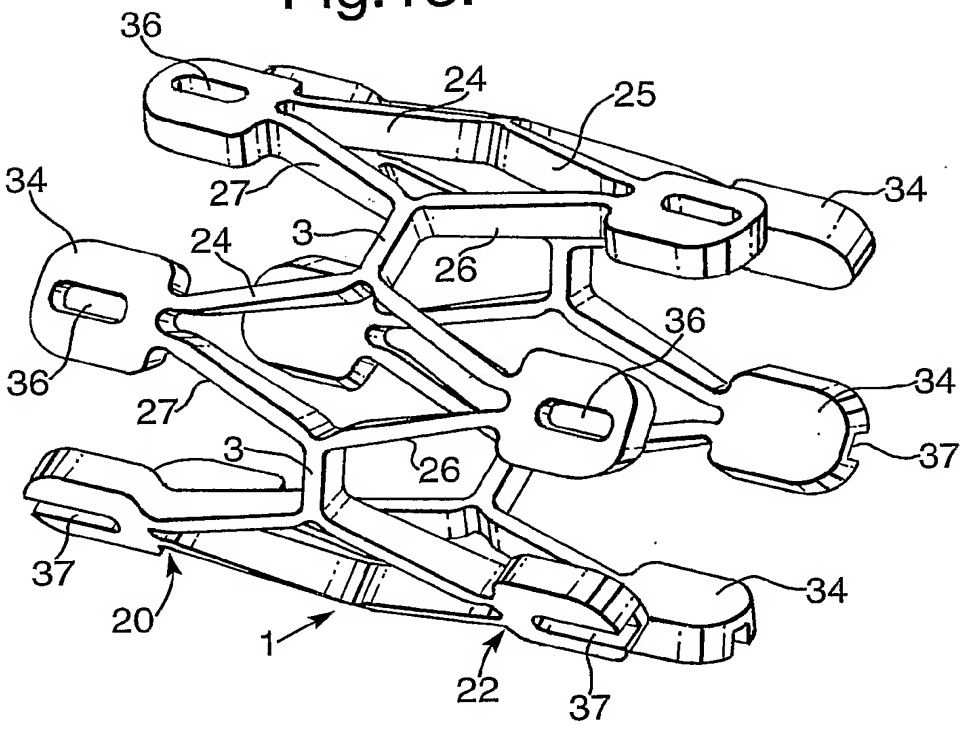

36
24
25
34
27
34
3
24
26
36
36
34
27
37
3
26
37
34
20
1
22
37

Fig.14.

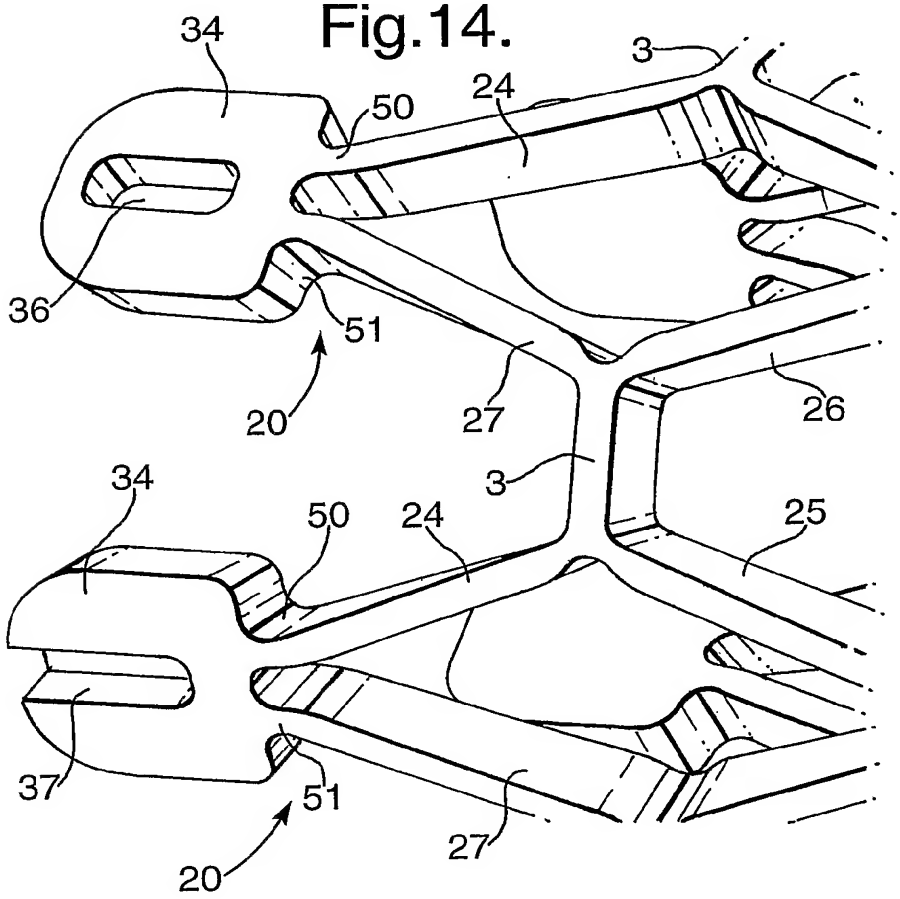

34
3
50
24
36
51
20
27
26
34
3
50
24
25
37
51
27
20

Fig.15A.

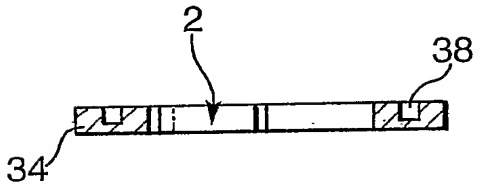


Fig.18A.

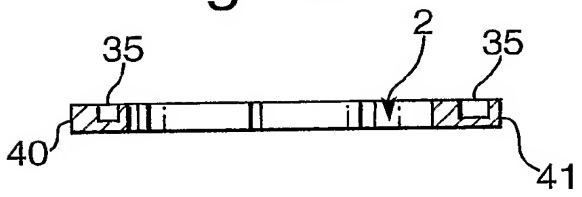


Fig.15.

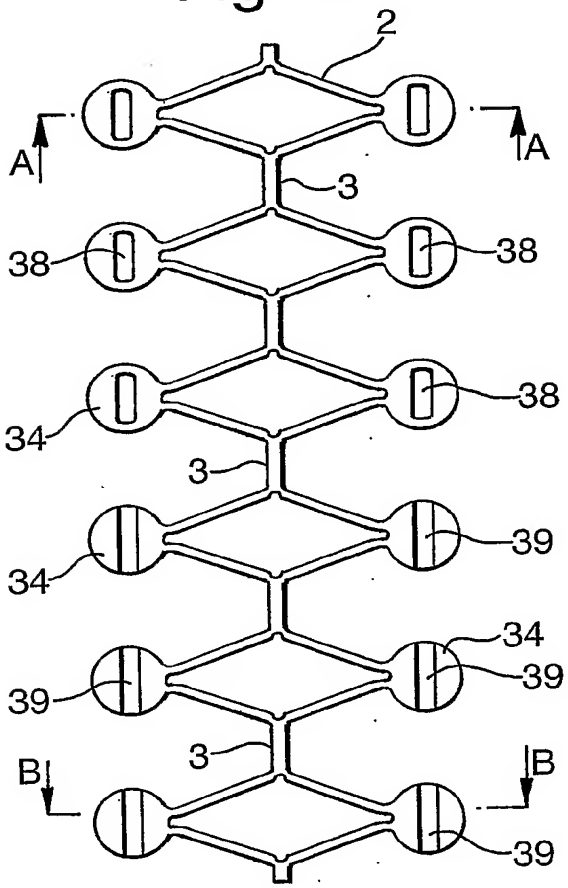
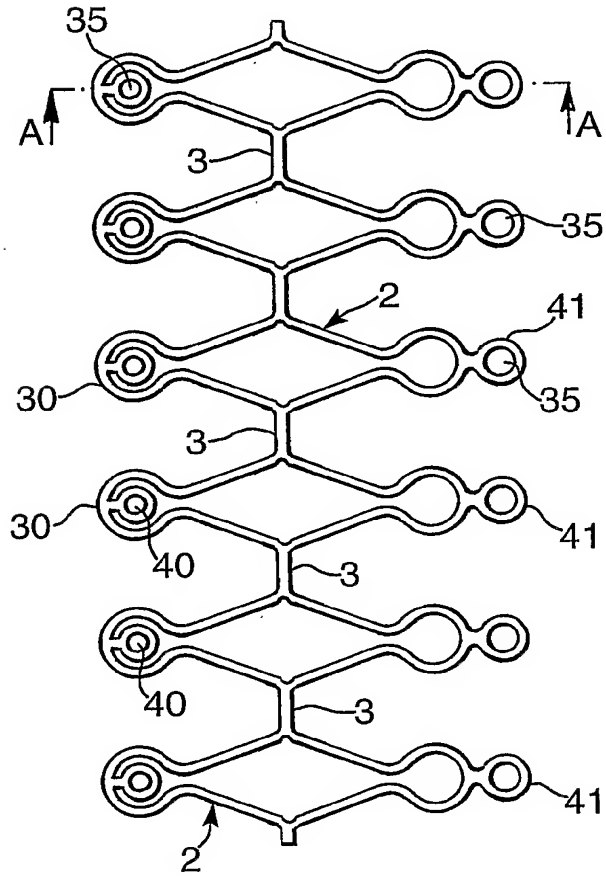


Fig.18.



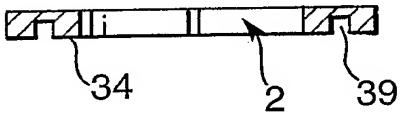


Fig.15B.

Fig.16.

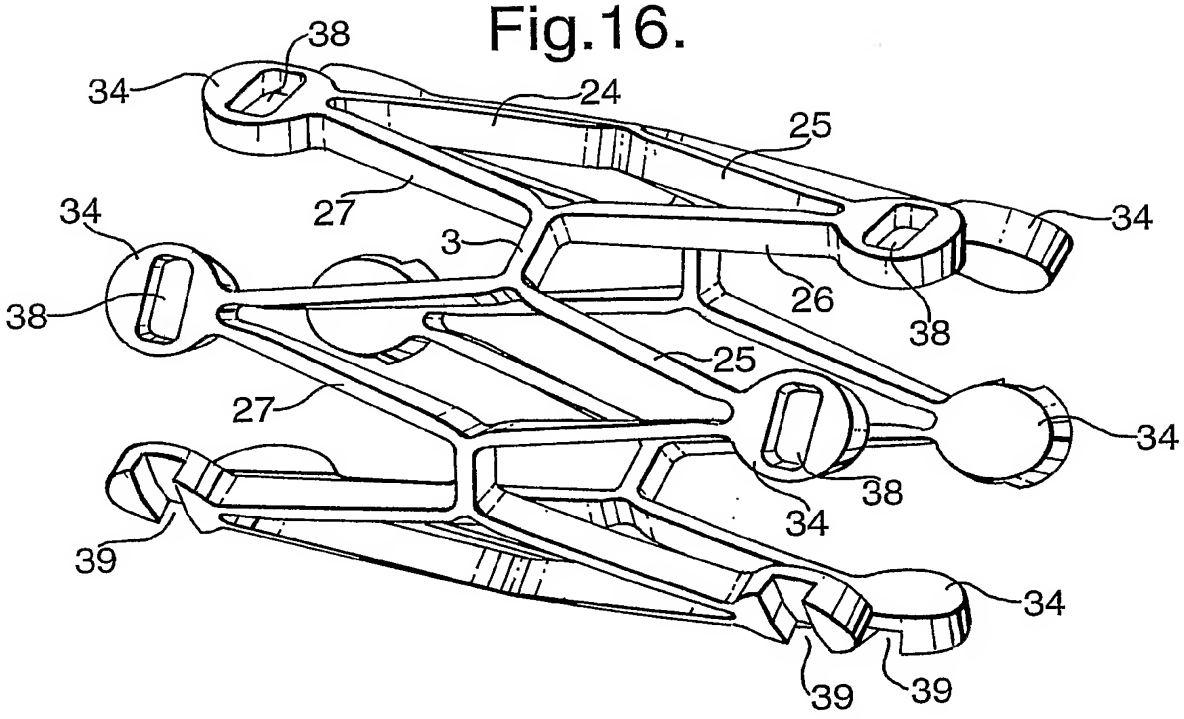

38
34
24
25
27
34
3
34
26
38
38
25
27
34
38
34
39
34
39
39

Fig.17.

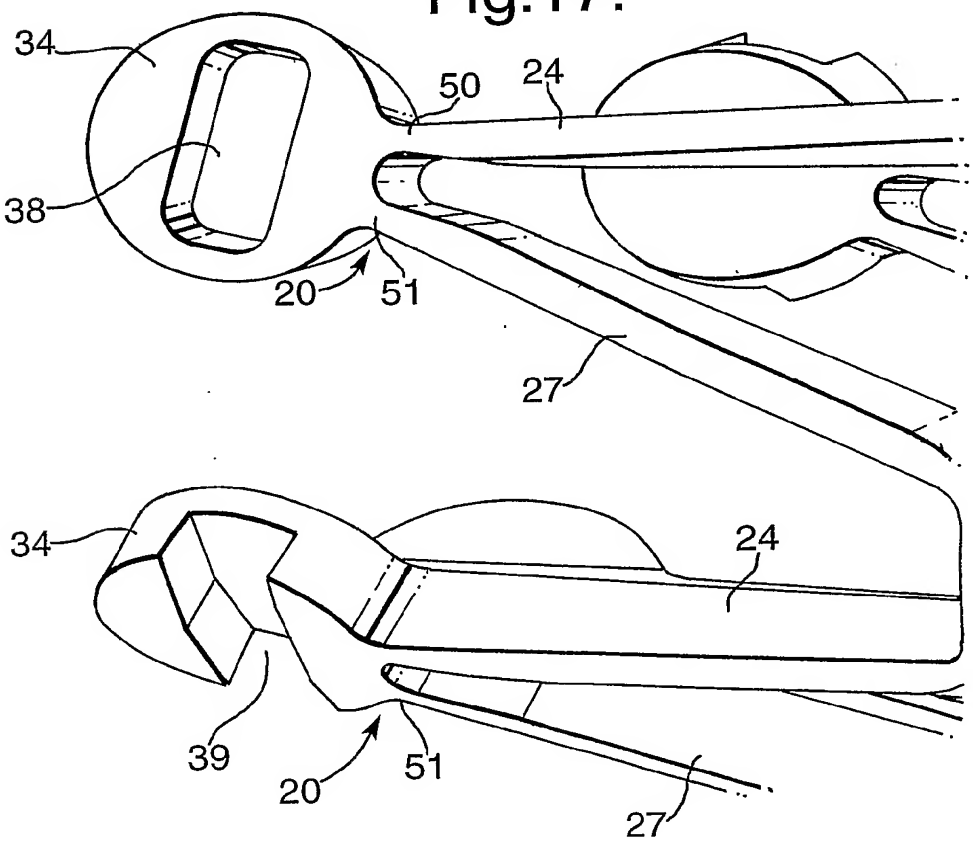

34
50
24
38
20
51
27
34
24
39
20
51
27

Fig.19.

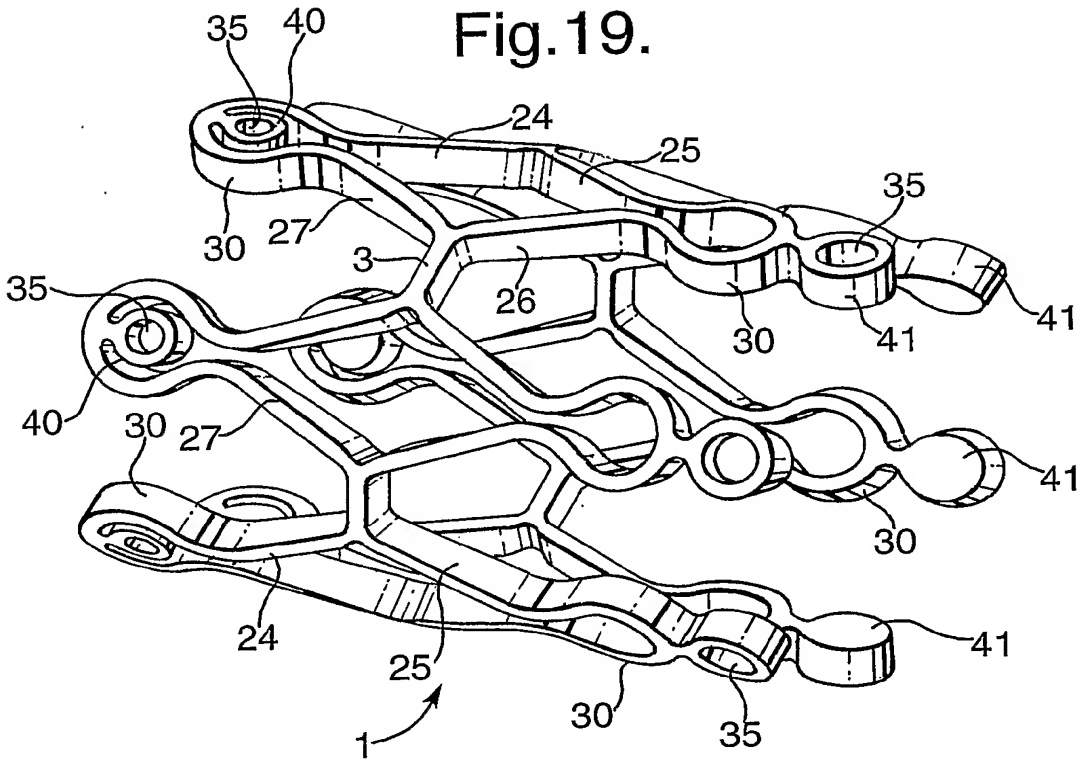


Fig.20.

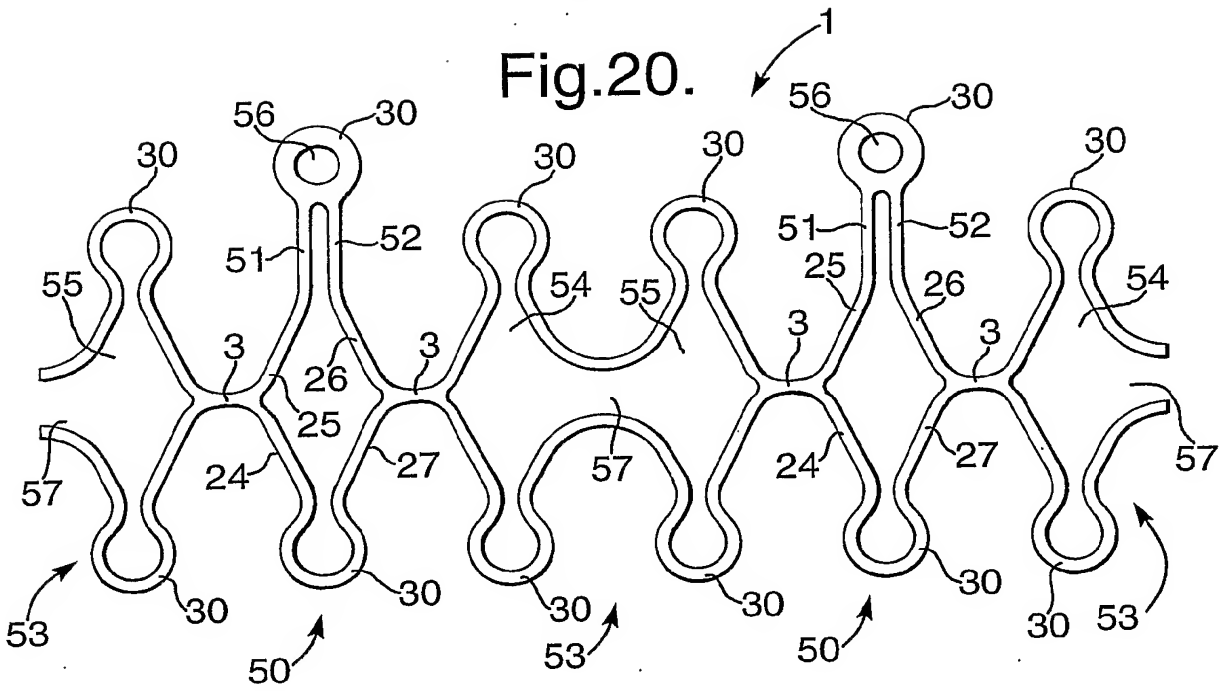

1
56
30
30
30
30
30
56
30
30
51
52
51
52
55
54
55
25
26
54
3
3
3
3
26
25
57
24
27
57
24
27
57
30
30
30
30
30
30
30
53
50
53
50
53

Fig.21.

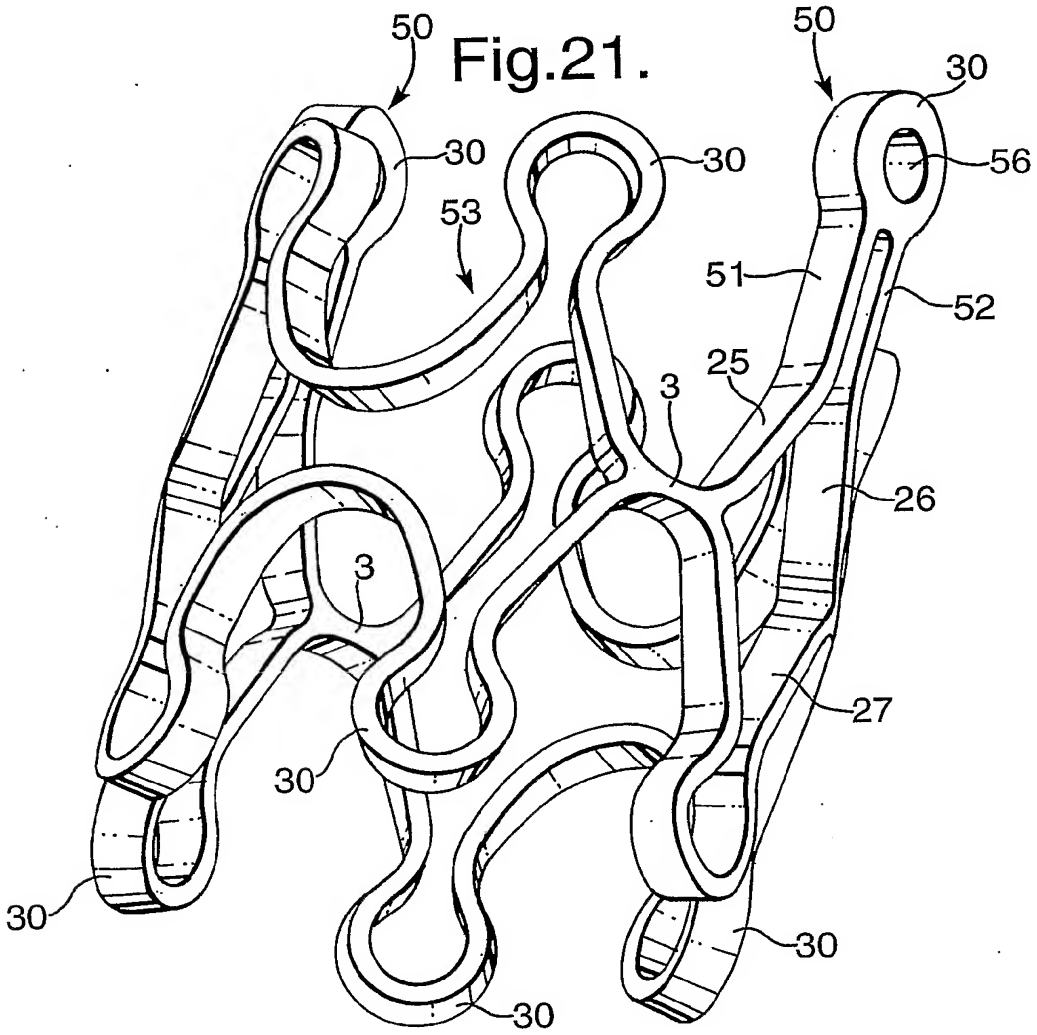

50
50
30
30
30
56
53
51
52
25
3
26
3
27
30
30
30
30

Fig.22.

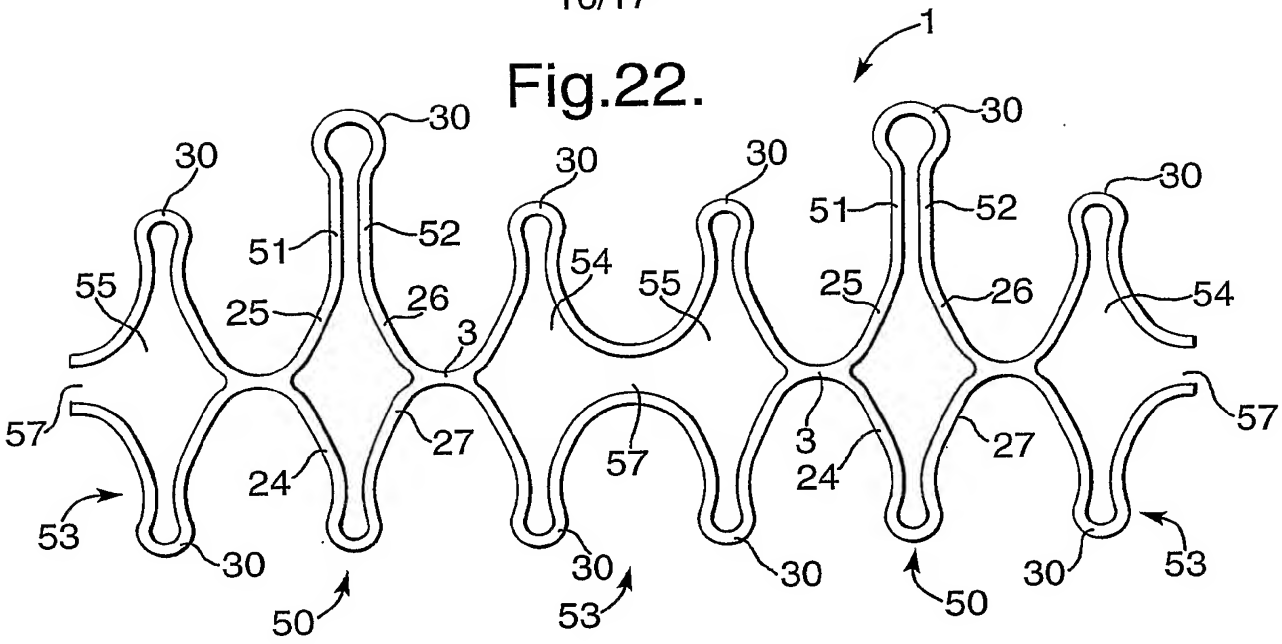
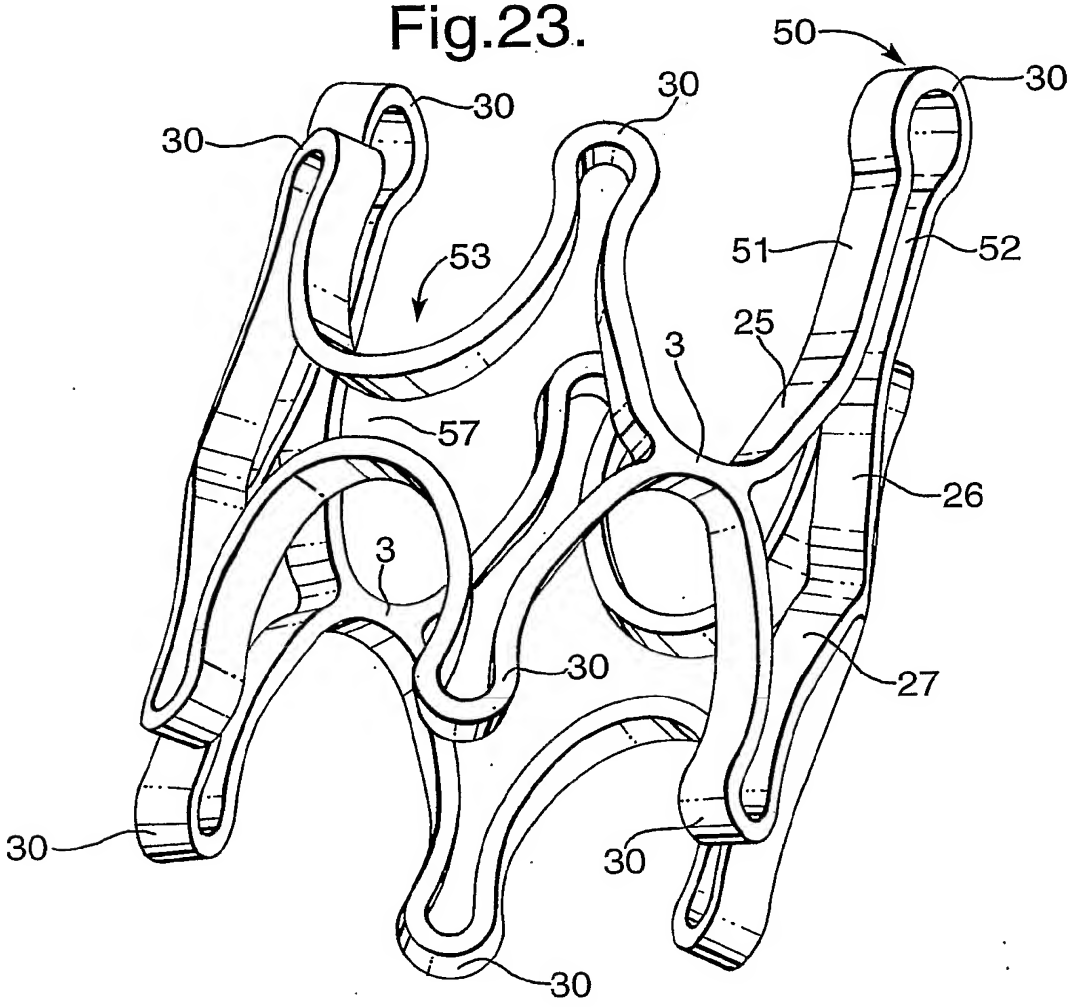

1
30
30
30
30
30
30
51
52
51
52
54
55
55
25
26
25
26
54
3
3
57
57
27
27
57
24
24
53
30
30
30
30
30
53
50
50
53

Fig.23.


50
30
30
30
30
30
53
51
52
25
3
57
26
3
27
30
30
30

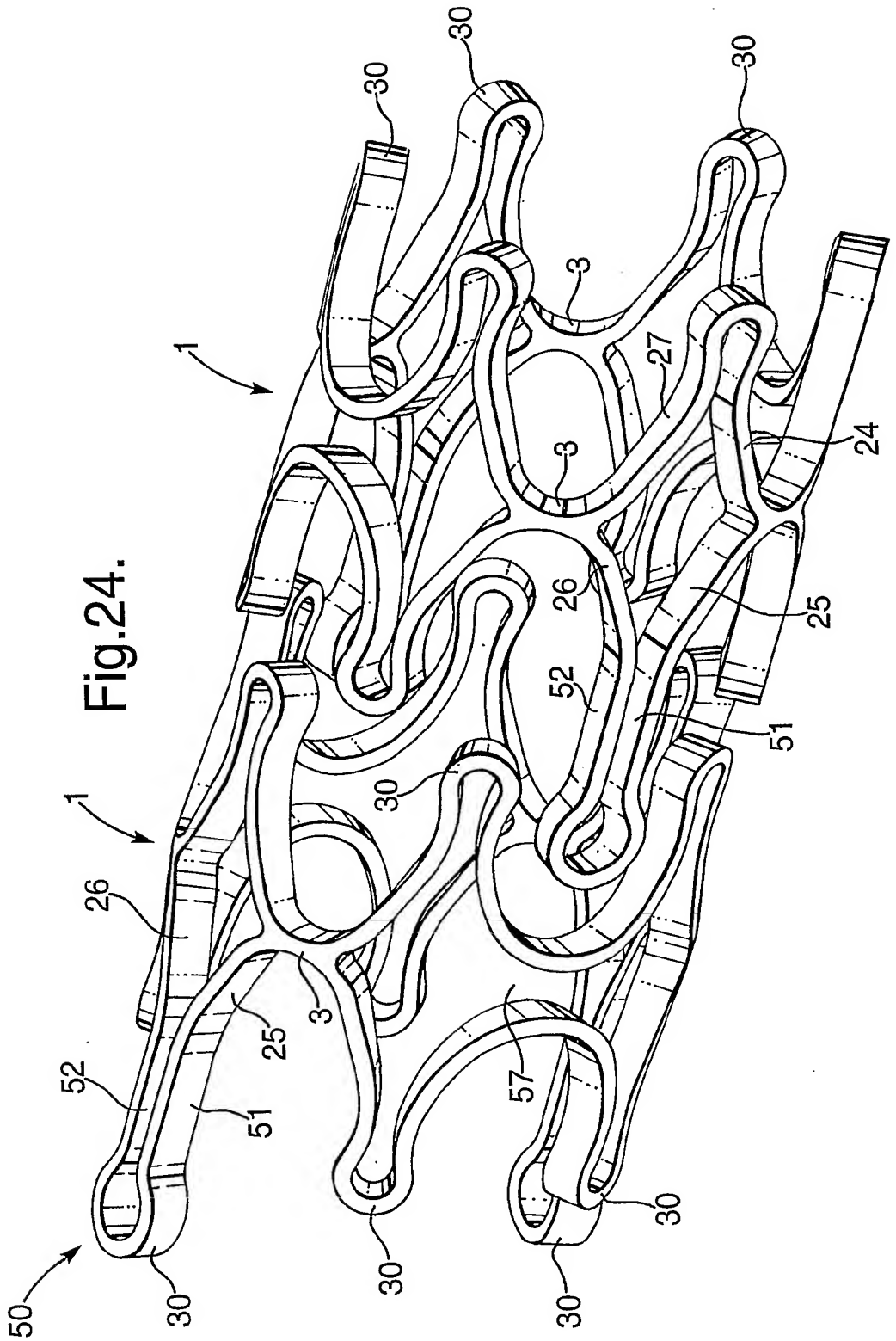


Fig.24.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/09931

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 122 154 A (RHODES VALENTINE J) 16 June 1992 (1992-06-16) column 7, line 4 - line 8 figures 1,8	1,2, 7-16,19, 20
Y		3-6,17, 18,21-28

Y	WO 00 15151 A (ISOSTENT INC) 23 March 2000 (2000-03-23) figures 3-6,8 page 6, line 28 -page 11, line 31	3-6,17, 18

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 December 2002	10/12/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US 2002/038146 A1 (HARRY ULF) 28 March 2002 (2002-03-28) claims 1-3 paragraph '0040! - paragraph '0044! paragraph '0046! paragraph '0050!	21-28
A	US 6 187 034 B1 (FRANTZEN JOHN J) 13 February 2001 (2001-02-13) column 4, line 57 -column 6, line 13	1-28
A	US 6 036 725 A (AVELLANET FRANCISCO J) 14 March 2000 (2000-03-14) column 5, line 18 -column 6, line 61	1-28
A	US 6 251 134 B1 (ALT ECKHARD ET AL) 26 June 2001 (2001-06-26) figures 2,3 column 5, line 3 -column 8, line 7	1-18
A	"DRUG DELIVERY STENT WITH HOLES LOCATED ON NEUTRAL AXIS" RESEARCH DISCLOSURE, KENNETH MASON PUBLICATIONS, HAMPSHIRE, GB, no. 429, January 2000 (2000-01), page 13 XP000976354 ISSN: 0374-4353 the whole document	1,21-28

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 02/09931

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5122154	A	16-06-1992	NONE		
WO 0015151	A	23-03-2000	AU	6144599 A	03-04-2000
			WO	0015151 A1	23-03-2000
US 2002038146	A1	28-03-2002	US	2001032011 A1	18-10-2001
			WO	02060349 A2	08-08-2002
US 6187034	B1	13-02-2001	NONE		
US 6036725	A	14-03-2000	NONE		
US 6251134	B1	26-06-2001	DE	19950756 A1	31-08-2000